

R E M A R K S

Claims 6, 8-12 and 14-17 are pending in the present application. The Examiner has made the following rejections:

1. Claims 6-11 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement;
2. Claims 12 and 14-17 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement;
3. Claims 6-11 stand rejected as allegedly obvious or anticipated by Cook et al. (U.S. Pat. No. 5,674,901);
4. Claims 12 and 14-17 stand rejected as allegedly obvious or anticipated by Cook et al. (U.S. Pat. No. 5,585,400).

Unless otherwise noted, the claims have been cancelled or amended to further Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000)), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future. None of the claim amendments made herein are intended to narrow the scope of any of the amended claims within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) or related cases. Support for the amendments may be found in the specification at page 13, lines 5-20, among other places.

1. Claims 6-11 are enabled

Claims 6 has been amended to claim a method of increasing CD4 and CD8 counts and as taught in the specification. Applicants note that these types of cells are white blood cells, and as such, Applicants believe the original rejection is in error. Nevertheless, Applicants respectfully submit that the claims are enabled.

2. Claims 12 and 14-17 are supported by an adequate written description

Claim 12 has been amended to claim a method of attenuating allergic reactions as taught in the specification. Since this embodiment was specifically taught at page 13 of the specification, Applicants respectfully submit that the claim is supported by an adequate written description. Applicants further note that this limitation does not further limit the originally drafted claims.

3. Claims 6-11 are not obvious or anticipated

Claims 6-11 stand rejected as allegedly obvious or anticipated by Cook et al. (U.S. Pat. No. 5,674,901). The Examiner admits that “the claims differ in that a ratio of 1.2:1 to 3:1 is given for the t10,c12 octadecadienoic acid and t9,c11 octadecadienoic acid respectfully” and the “ratios are not specifically taught.” Applicants respectfully submit that because these elements are not taught, there can be no anticipation of the claims as anticipation requires that each and every element of the claims be taught by the cited reference.

With respect to obviousness, Applicants respectfully submit that a *prima facie* case of obviousness requires the Examiner to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue.¹ In addressing this rejection, Applicants focus on the independent claims since the non-obviousness of independent claims necessarily leads to the non-obviousness of the claims dependent thereon.²

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because, as noted above, the Cook patent simply fails to teach the CLA

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

² §MPEP 2143.03.

compositions recited in the claims.

Furthermore, the Examiner has failed to provide a sufficient reason to modify Cook to teach the claimed invention. As an alleged motivation to modify, the Examiner states that "it is clearly stated in col. 8 that it would be obvious and readily apparent to those skilled in the art to modify or make changes without departing from the spirit and scope of the invention." With respect to claims 6-11, this is a conclusory motivation statement because there is no teaching to modify Cook by altering ratios of the isomers making up CLA. A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine or modify. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)). Specifically, the Federal Circuit held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**³

Furthermore, an Examiner may not simply rely on conclusory statements even for what they think might be common sense or well known in the art:

The 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 that 'deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.' The Board's findings must extend to all material facts and must be documented on record, lest the 'haze of so-called expertise' acquire insulation from accountability. 'common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.'⁴

Basically, the Examiner is relying on common knowledge and common sense because the Cook says nothing about what modification can be made (i.e. altering isomer ratios). In particular, there is no objective evidence the Examiner can point to regarding the desirability of altering isomer ratios to obtain better results. Indeed, the Cook patent does not even enable the production of such compositions with altered isomer ratios, much less suggest the desirability of making and testing such compositions.

³ *See, In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

⁴ *Id.* at 1344-1345.

Accordingly, Applicants respectfully submit that claims 6-11 are not obvious and should be passed to allowance.

4. Claims 12 and 14-17 are not anticipated or obvious

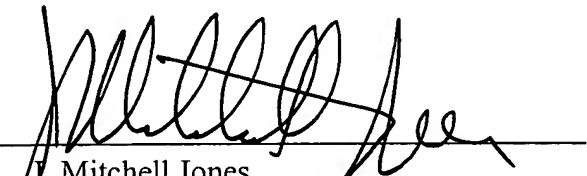
Claims 12 and 14-17 stand rejected as allegedly obvious or anticipated by Cook et al. (U.S. Pat. No. 5,585,400). For the same reasons as with claims 6-11, claims 12 and 14-17 are not obvious or anticipated. As admitted by the Examiner (“although the ratios are not specifically taught”), the Cook patent does not teach how to make or use the claimed CLA compositions. Thus, there is no anticipation or *prima facie* obviousness as the cited reference does not teach each element of the claims. Moreover, the Examiner has not established a sufficient basis for modifying the reference and instead again relies on a non-specific statement in the cited reference – “it would be obvious and readily apparent to those of skill in the art to modify or make changes without departing from the spirit and scope of the invention.” As explained above, this statement is conclusory, non-specific, and fails to provide any motivation to alter the ratios of isomers in the CLA composition. As such, the Examiner has failed to establish a *prima facie* of obviousness. Applicants respectfully request that the claims be passed to allowance.

Conclusion

All grounds of rejection and objection of the Office Action of October 20, 2004 having been addressed, reconsideration of the application is respectfully requested. It is respectfully

submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: January 20, 2005



J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard St., Suite 350
San Francisco, California 94105
608/218-6900